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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,383	02/05/2004	Daqing Che	P1054US00	3324

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EXAMINER	
PAGONAKIS, ANNA	
ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
03/16/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/771,383	CHE ET AL.	
	Examiner	Art Unit	
	ANNA PAGONAKIS	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-17,19 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-17, 19 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 11/19/2010 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Change of Examiner

The examiner assigned to the instant application has changed. The new examiner is Anna Pagonakis. Contact information is provided at the end of the Office Action.

Status of Claims

Claims 1, 3-17, 19 and 23 are currently under examination and the subject matter of the present Office Action.

Claim Rejection – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-17, 19 and 23 are rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,087,511 [hereinafter referred to as "Lin et al"](the reference is being considered in its totality)[1].

[1] Lin et al is cited on Applicants' IDS.

Lin et al disclose a novel process for making amorphous atorvastatin hemi calcium salt, noting that the same is useful as an inhibitor of HMG-CoA and therefore, useful in the treatment of hypercholesterolemia (Col. 1, lines 13-21). The disclosed process comprises beginning with a mixture comprising atorvastatin lactone and methanol reacted with an aqueous solution of sodium hydroxide to form an open-ring sodium salt. The organic layer is discarded and the aqueous layer is extracted with MTBE. When the organic layer is again discarded, the aqueous solution of the sodium salt is heated and to the solution added calcium acetate hemihydrate dissolved in water. Shortly thereafter, the mixture is seeded with a slurry of crystalline atorvastatin. Some time thereafter, the mixture is heated, then cooled, filtered, and wished with a solution of water and methanol followed by water. The resulting atorvastatin solid is dried under a vacuum to give the crystalline form, and through a process disclosed in Example 2, the crystalline form because amorphous atorvastatin (Col. 5, lines 11-65)..

The adjustment of particular conventional working conditions such as quantity of seeds of amorphous atorvastatin calcium relative to the weight percent of atorvastatin lactone and the stoichiometry of sodium hydroxide relative to the same, and the timing of the hydrolysis reaction are mere matters of routine optimization and judicious selection well within the purview of one of ordinary skill in the art.

One of ordinary skill in the art would have been motivated to perform the instant invention based on the disclosures in Lin et al because as noted therein, although amorphous atorvastatin solids were known to exist in advance of the advent of crystalline atorvastatin, "the production of amorphous atorvastatin by the previously disclosed processes was not consistently reproducible (Col. 1, lines 61-65). Further, it was also known that the bioavailability patterns of drugs often differ based on whether their forms are amorphous or crystalline, for example, making it desirable to have a procedure for converting the crystalline form to the amorphous form (Col. 2, lines 1-7).

In view of the foregoing, it would have been prima facie obvious to one of ordinary skill in the art to prepare amorphous atorvastatin calcium by the hydrolysis of atorvastatin lactone to form atorvastatin sodium salt, to suspend the same into a solution of aqueous calcium acetate, and then, to isolate and dry the same to form amorphous atorvastatin calcium salt and that the same would be effective in the treatment of hypercholesterolemia.

Claims 4-7 are rejected under 35 U.S.C. §103(a) as being obvious over Lin et al in view of U.S. Patent Pre-Grant Publication No. 20050267198 A1 [hereinafter referred to as "Tessler et al"].

Tessler et al teach that amorphous atorvastatin hemi-calcium may be prepared by treating any other form of atorvastatin hemi-calcium with acetone at room temperature to reflux temperature for between a few hours and 25 hours, preferably about 16 hours (Page 7, Para. 89). A preferred starting material is Form V and moreover, amorphous atorvastatin hemi-calcium also may be prepared by ball milling of any crystalline form of atorvastatin hemi-calcium (Page 7, Para. 91; Page 12, Claim 119).

One of ordinary skill in the art would be motivated to combine the teachings of Tessler et al with the teachings of Lin et al to arrive at the instant invention given the overlap in scope of the teachings in both references, most notably, the crystalline form of atorvastatin, how it is prepared and used in other forms of atorvastatin.

In view of the foregoing, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was contemplated to prepare amorphous atorvastatin.

Applicant repeatedly alleges that step b) is not disclosed by Lin et al. and Tessler et al. This is not found persuasive. . As part of the process, when the organic layer is again discarded, the aqueous solution of the sodium salt is heated and to the solution added calcium acetate hemihydrate dissolved in water. Shortly thereafter, the mixture is seeded with a slurry of crystalline atorvastatin. Some time thereafter, the mixture is heated, then cooled, filtered, and wished with a solution of water and methanol followed by water. The resulting atorvastatin solid is dried under a vacuum to give the crystalline form, and through a process disclosed in Example 2, the crystalline form because amorphous atorvastatin (Col. 5, lines 11-65). Thus, Lin et al. teach that the addition of atorvastatin sodium salt solution to an aqueous calcium acetate solution, e.g., calcium acetate hemihydrate dissolved in water. Therefore, the claimed limitation of step b is taught by the prior art.

Conclusion

No claim is found to be allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 7am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Brandon J Fetterolf/
Supervisory Patent Examiner, Art Unit 1628